PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q102803
Takahide OHISHI, et al.	
Appln. No.: 10/511,549	Group Art Unit: 1657
Confirmation No.: 9316	Examiner: Lisa Joe HOBBS
Filed: October 18, 2004	

For: SCREENING METHOD OF AGENTS FOR INCREASING INSULIN CONTENT

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on June 26, 2008:

REMARKS

An Examiner's Interview Summary Record (PTO-413) was mailed July 2, 2008.

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: Two submissions on pancreatic cells and functions.

2. Identification of claims discussed: Claims 7, 13, 15 and 17.

3. Identification of art discussed: all of record, particularly Chen et al., U.S. Patent No. 7,108,991.

4. Identification of principal proposed amendments: None

5. Brief Identification of principal arguments: None

6. Indication of other pertinent matters discussed: The relationship of instant Claim 7 to Chen *et al.* Claim 1 was discussed. The particular teaching in the specification of Chen *et al.* that support Claim 1 were discussed. The state of the art in June 1999 (Chen *et al.* priority date) vs. Sept 2002 (instant priority date) was discussed with respect to the amount of knowledge about the ability of the polypeptide of SEQ ID NO:2 (Chen *et al.* SEQ ID NO:8) to detect compounds which "promote" insulin production. The specific meaning of the word "regulate" from Chen *et al.* Claim 1 was discussed.

Possible ways to distinguish the instant assay from the Chen *et al.* assay were discussed. Further information from those of skill in the art regarding the polypeptide of SEQ ID NO:2 (8) and its relationship to insulin production was discussed. How best to particularly point out and distinctly claim the specific instant method, thus distinguishing it from the general Chen *et al.* method, in the response to the Non-Final Rejection of April 11, 2008 that will be filed was discussed.

7. Results of Interview:

Applicants thank the Examiner for the telephone interview with Applicants' representatives, Susan J. Mack and Tu A. Phan, on June 26, 2008 to address the § 102(e) rejection to Chen.

During the telephone interview, Applicants' representative presented background information to establish that because the pancreas performs two different functions (endocrine and exocrine) and the functions are also performed by different cells, the mere identification of a protein in the pancreas without further specific evidence is insufficient to demonstrate the

protein's involvement with insulin regulation. This position is further supported by the disclosure in each of the seven documents cited in the Amendment filed March 3, 2008. Although each of the seven documents identified proteins specific to the pancreas, the proteins were not involved in insulin regulation Similarly, Chen merely identified the expression of RUP3 in the pancreas without further evidence to show its involvement in insulin regulation. The Examiner appeared to understand and agree with these arguments, i.e., that because of the different functions performed by the pancreas and the different pancreatic cells involved with these different functions, the function of a protein cannot necessarily be predicted based upon its expression in the pancreas alone.

However, the Examiner pointed out that claims 1-11 of Chen recite a method for identifying compounds for regulating insulin concentration, and the term "regulation" encompasses the increase in insulin production claimed in Applicants' method. The Examiner mentioned that it appears Applicants' position is that because Chen does not provide sufficient specific disclosure of measuring insulin, i.e., to determine whether insulin is up-regulated or down-regulated, Chen's disclosure is non-enabling. The Examiner stated that she cannot accept such arguments because such arguments attack the validity of a patent which under standard U.S. practice holds a strong presumption of validity on its face.

Nevertheless, the Examiner suggested that Applicants may wish to address the rejection by providing evidence such as published literature articles to support the position that although regulation of insulin was a good assumption at the time of Chen's invention, the knowledge in the art between that time (1999) to the time the present application was filed (2004) either taught

away from the role of RUP3 in up-regulating insulin or established that the role of RUP3 in insulin regulation was unpredictable so that one of ordinary skill in the art would not have expected the increase in insulin production demonstrated by the claimed invention. In other words, the Examiner suggested Applicants may wish to provide state of the art evidence to support that the claimed invention is separately patentable from Chen.

In addition, the Examiner stated that recitation of specific limitations in the claim will help to further differentiate the claimed invention from Chen. In this regard, the Examiner acknowledged that the step of confirming recited in claim 13 does not appear to be explicitly disclosed by Chen, however, the Examiner considers it inherent in the method claimed by Chen. The Examiner mentioned that Applicants may wish to amend claim 7 to either recite a particular buffer that is used in the assay, specify how the polypeptide is analyzed, or specify a specific amount to which the polypeptide is activated.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

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